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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,313	08/18/2003	Atsuko Fukui	RYUK.001RE	4219

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,313	FUKUI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reissue Applications

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Response to Amendment

The amendment to the claims filed on 07/09/04 does not comply with the requirements with 37 CFR § 1.173. Any amendment to the description and claims in reissue application must be made in accordance with § 1.173. An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression "amended," "twice amended," etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without presentation of the text of the claim. Added claims must be entirely underlined. Amendment that make deletions to the claims should not include struck-thru.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "packaged in a prepared form in the absence of a medication" in claims 1 and 6; and limitation "prepared form" in claims 11 and 13. Further clarification is suggested. In accordance with MPEP § 714.02, applicant should specifically point out support for any amendments made to the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected in the use of the phrase "swallowing the combination in conjunction with the combining step". It is unclear how the combination is swallowed *in conjunction* with the combining step, since the combining step is to make the "combination", and then, the "combination" is being swallowed. Shouldn't the "combination' be swallowed after the combining step? Further clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speck et al. US 5,010,061.

The patent discloses compositions comprising guar flour mixed with a corresponding volume of aqueous liquid and drink within 0-5 minutes after complete mixing (See col. 3, lines 27-31), and teaches that drugs, vitamins, minerals and all kinds of contrast media can be added to the flour (See col. 3, lines 32-51). In the examples provided, the guar flour is suspended in water and drunk soon after (See Examples 1-4), or the guar flour is mixed with a medicine or contrast agent, the mixture is suspended in water and drunk soon after (See Examples 5-8). The patent teaches that the composition can be administered orally for the treatment of diseases, including intestinal peristalsis and diabetes (col. 3, lines 32-43; and claims 1, 4-21). The patent also provides the general teaching, that indigestible polysaccharides, such as agar and guar, swell in water and form viscous jellies (See col. 1, lines 8-25).

Thus, the patent discloses drinkable compositions comprising water and a paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid, as claimed in instant claims 1, 2, 6, 7, 2 1 and 23, and methods for taking a medication, as claimed in instant claims 11, 13, 1 5, 17, 19 and 20. The patent is deficient in the sense that it

does not specifically disclose the viscosity range and the gel strength of the gel, however, the patent teaches that solutions of sufficiently low viscosity can be obtained by mixing the guar with water, and said solutions can be drunk (See col. 1, lines 60-62). Furthermore, it is the position of the examiner that because the patent teaches the same ingredients and same compositions as Applicant, it would flow that the invention disclosed by the patent would have the same viscosity range and gel strength as the invention claimed by Applicant. The burden is shifted to Applicant to provide evidence that the two compositions exhibit different properties, if this is the characteristic to be relied upon to show patentable distinction. Absent such an evidence, this invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

With regard to claims 3, 8, 22 and 24, the patent teaches that aqueous suspensions are preferred, in which the content of the guar flour is at least 2% (See col. 3, lines 67-68). Furthermore, Example 3 teaches that 4 grams of guar flour are suspended in 150 ml cold water and drunk rapidly. The mixture disclosed by the patent produces a solution of 2.6% guar and 97.4% water, which is in the range claimed by Applicant.

Regarding claims 4, 5, 9, 10, 12, 14, 16 and 1 8, the examples provided in the patent indicate that the guar flour is mixed with drugs, vitamins or contrast agents in solid form (See Examples 5-8). It is the position of the examiner that, due to the nature of the mixture disclosed by the patent, said drugs, vitamins or contrast agents are mixed in powder form, as claimed by Applicant. Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to apply the teachings of Speck et al. to device drinks to help individuals swallowing a medication, and methods for administering a medication, comprising swallowing said drinks. The expected result would have been a successful drug delivery composition and successful methods for administering drugs. Because of the teachings of Speck et a1., that drugs, vitamins and contrast agents can be added to guar flour, mixed with water and drink immediately, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in assisting an individual in swallowing a drug. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 07/09/04 have been fully considered but they are not persuasive.

Applicant argues that claims 1 and 6 are patentable over Speck in view of the product-by-process limitation "packaged in a prepared form in the absence of a medication prior to enwrapping the medicine". In response to the applicant's argument, applicant has not pointed out support for the amendments made. Furthermore, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Applicant also amends claims 11 and 13 to include the limitation "in a prepared form". Similarly, applicant has not pointed out support for the amendments. Furthermore, no criticality is seen in the particular limitation, because Speck teaches drinkable compositions comprising water and a paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid, as claimed in instant claims 1, 2, 6, 7, 2 1 and 23. No unusual and/or unexpected results have been shown in the use of "a prepared form" over those disclosed by Speck. Accordingly, the 103(a) rejection over Speck is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600